

**Application No.: 10/583500**  
**Filing Date: June 19, 2006**

### **REMARKS**

In response to the Office Action, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

#### **Discussion of the Claim Rejections Under 35 U.S.C. § 103**

Claims 7 and 8 have been rejected under 35 U.S.C. § 103 as being unpatentable over Vermeer (U.S. Patent Number 5,624,906). Applicant respectfully submits that Claims 7 and 8 are allowable over Vermeer, as discussed below.

#### **Discussion of Patentability of Independent Claim 7**

Claim 7 recites, among other things, “an antibacterial agent having...a base containing polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 4000, and propylene glycol. In previous response, Applicant argued that Vermeer merely lists the claimed ingredients as a part of his list having over 30 ingredients and does not teach the specific combination recited in Claim 7. In rejecting the claim, the Examiner acknowledged that the reference discloses about 30 ingredients and asserts that most of these ingredients are polyethylene glycols and the reference further teaches mixtures of these ingredients, thereby suggesting the instantly claimed combination.

However, as discussed below, the particular combination of glycol recited in Claim 7 is a critical feature that results in unexpected results that one having ordinary skill in the art could in no way predict.

The treatment composition comprising the claimed components possesses improved operability and penetrability of the treatment composition and improved soaking properties for its administering to teeth so that bacterial intraoral diseases can be treated without depending on removal of living tissues. See previously presented Applicant’s Declaration under 37 C.F.R. § 1.132, and abstract. Nothing in the prior art would lead one having ordinary skill in the art to expect this result. Therefore, even if prima facie case of obviousness were established, the unexpected result would rebut any such case.

Discussion of Examiner's Response to Declaration

Efficacy of PEG 400 and PEG 4000 alone

The Examiner indicated that data should be submitted for a composition comprising PEG or PEG 4000 alone. However, as described in Applicant's specification from page 10, lines 15 to page 11, line 6 and the Declaration, the composition comprising PEG 400 or PEG 4000 alone, unlike the claimed composition, does not provide ease of loading onto administering tools and administering to teeth, or sterilizing effect against fungi. Accordingly, the composition comprising PEG 400 or PEG 4000 alone would be inoperable and have not efficacy for the intended purpose. Sample 1 which consists of water is merely a control to evaluate the penetrability of Sample 2 to 6, and is not a sample for evaluation as a treatment composition.

Experiment 2

The Examiner indicated that it cannot be concluded that the effect of improved penetrability by the combination with PEG 600 cannot be concluded because Experiment 1 and Experiment 2 were not carried out under the same conditions and that even though the compositions of Samples 3 and 7 appear to be similar, their results are different.

However, as explained by the inventor in a Declaration filed herewith, the conditions for Experiments 1 and 2 are the same, and the migration distance of Sample 7 is the same as the migration distance of Sample 3.

New Experiments

In Experiment 2, Sample 8 actually has a longer migration distance than Sample 7, but because of the limitation of the length of the tooth root, the difference in migration distance is actually not that large. Further, as stated in the Declaration, the inventor carried out new experiments to evaluate the movement range (in particular, in the direction of the width of the tooth root).

While Sample 9 (PEG400:PEG4000:PG = 25:25:50) moved to the vicinity of the tip of the in the direction of the length of the tooth root, the portion over which it spread in the width direction was only is a narrow area in the vicinity of the base portion of the tooth root and the tip.

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In contrast, Sample 10 (PEG400:PEG60:PEG4000:PG = 19:13:24:44) moved to the vicinity of the tip in the length direction of the tooth root, and further, the portion over which it spread in the width direction spans a wide area from the base portion of the tooth root to the tip.

From this, it can be understood that the claimed treatment composition comprising PEG400, PEG600, PEG4000 and PG is capable to obtain the effect that the composition penetrates not only for a long distance, but also spans a wide area. This effect is very important for certain and completes treatment of tooth disease (for example tooth decay).

Thus, it appears from both the earlier declaration and the newly submitted declaration that the base including the particular combination of PEG 400, PEG 600, PEG 4000, and PG of the claimed composition possesses superior penetrability, which eliminates removal of living tissues to treat bacterial intraoral diseases. Applicant respectfully submits Claim 7 is allowable over the cited references.

#### Discussion of Patentability of Dependent Claim 8

Claim 8 depends from Claim 7, and further defines additional technical features of the present invention. In particular, Claim 8 recites ratios of each component, which cited reference is silent about. In view of the patentability of Claim 7, and in further view of the additional technical features, Applicants respectfully submit that the dependent claims are patentable over the prior art.

#### Request for rejoinder

Claims 1-6 and 13-16 are dependent on at least one of the elected claims. Accordingly, in accordance with M.P.E.P. 821.04, Applicants request rejoinder and examination of these claims upon allowance of the elected claims (7 and 8).

### **CONCLUSION**

In the light of the applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the

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application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

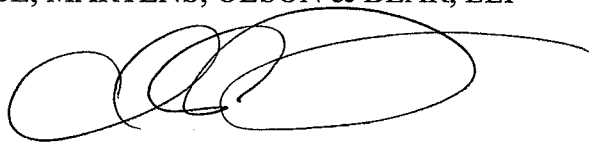
*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP



Dated: March 17, 2011

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of : Toyohiko TAKUSHIGE and Etsuro HOSHINO  
Serial No. : 10/583,500  
Filing Date : 06/19/2006  
For : Bacterial Intraoral Disease Treatment Composition  
Examiner : Lezah ROBERTS  
Art Unit : 1612

Honorable Commissioner of Patents and Trademarks  
P. O. Box 1450  
Alexandria, Virginia 22313-1450

**DECLARATION UNDER 37 CFR §1.132**

I, Toyohiko TAKUSHIGE, a citizen of Japan, do hereby declare the following:

1. I am one of the joint inventors in the above-identified pending United States patent application, and am familiar with the specification, claims, and file history thereof.
2. I graduated from the School of Dentistry, Tohoku University in March, 1972. I obtained my license to practice as a dentist in June, 1972.  
I obtained the degree of Doctor of Medical Dentistry from Niigata University in October, 2004.
3. I became a research assistant in the School of Dentistry, Tohoku University in April, 1972, and have been a Professor in the Graduate School of Dentistry, Tohoku University, since April, 2005.  
I opened a dental clinic in Sendai City in November, 1980, where I currently practice.
4. I have reviewed the Office Action dated November 11, 2010 issued for the above-referenced patent application, in which Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vermeer (U. S. Patent No. 5,624,906).
5. The conditions of Experiment 2 described in my declaration of November 6, 2009, were carried out in order to evaluate the effect on penetrability of Samples #7 and #8. Sample #8 is a composition in accordance with the claimed invention, while Sample #7 lacks PEG600. Sample #8 has PEG400: PEG4000: PPG in a volume ratio of 20:40:40 and Sample 8 has PEG400: PEG600: PEG4000:PPG in a volume ratio of 22.2: 22.2: 22.2: 33.3.

6. The additional experiments described below were performed by me, or under my direction. The experiment in the attached documents refers to Test Example 1 of the specification. This experiment was carried out under the same conditions as Experiment 1 and Experiment 2, with the exception of the point of using Samples 9 and 10. Sample 9 includes PEG400, PEG4000 and PG in a ratio of PEG400:PEG4000:PG = 25:25:50. Sample 10 includes PEG400, PEG600, PEG4000 and PG in a ratio of PEG400:PEG600:PEG4000:PG = 19:13:24:44. Sample 9 moved to the vicinity of the tip in the direction of the length of the tooth root, while the portion over which it spread in the width direction is only a narrow area of the vicinity of the base portion of the tooth root and the tip. In contrast, Sample 10 moved to the vicinity of the tip in the length direction of the tooth root, and further, the portion over which is spread in the width direction spans a wide area from the base portion of the tooth root to the tip. In this way, it can be understood that by including all of PEG400, PEG600, PEG4000 and PG, the effect is shown that the composition penetrates to span not only a long distance, but also a wide area. This effect is very important for certain and complete treatment of tooth diseases (for example tooth decay).

7. I hereby declare that all statements made herein are to my own knowledge true and that all statements made on information and assumptions are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

9. March, 2011.

Date

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Toyohiko TAKUSHIGE

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